



EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
Molecular Biology and Genomics Unit



EUROPEAN UNION REFERENCE LABORATORY
FOR GENETICALLY MODIFIED FOOD AND FEED

**ANNUAL WORK PROGRAMME FOR 2012 ACTIVITIES
CARRIED OUT FOR THE IMPLEMENTATION OF
REGULATION (EC) No 882/2004**

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1. BACKGROUND INFORMATION

The Molecular Biology and Genomics Unit (MBG Unit) is one of the five scientific Units of the Institute for Health and Consumer Protection of the European Commission's Joint Research Centre (JRC). It provides scientific and technical support to the policy development under the European Commission regulatory framework for Genetically Modified Organisms (GMOs) and the development of biotechnology expertise in areas relevant to health and consumer protection. Since 2004 it exercises the mandate of Community Reference Laboratory for Genetically Modified Food and Feed¹.

Reference to the same CRL is made for GMOs in Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules².

Article 32 of Regulation (EC) No 882/2004 lays down the duties and tasks of CRLs. In particular, the Community reference laboratories for feed and food referred to in Annex VII shall be responsible for:

- (a) providing national reference laboratories with details of analytical methods, including reference methods;
- (b) coordinating application by the national reference laboratories of the methods referred to in (a), in particular by organising comparative testing and by ensuring an appropriate follow up of such comparative testing in accordance with internationally accepted protocols, when available;
- (c) coordinating, within their area of competence, practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field;
- (d) conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;
- (e) providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses;
- (f) collaborating with laboratories responsible for analysing feed and food in third countries.

Due to the implementation of the Lisbon Treaty on the European Union, CRL has been replaced by EURL (European Union Reference Laboratory).

¹ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1.
Commission Regulation (EC) 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms. OJ L 368, 23.12.2006, p. 99–109.

² OJ L 165, 30.4.2004, p. 1, as corrected by OJ L 191, 28.5.2004, p. 1

The majority of National Reference Laboratories (NRLs) nominated under Regulation (EC) No 882/2004 and responsible for GMO analysis have also been nominated NRL under Regulation (EC) No 1981/2006 and as a consequence are part of the European Network of GMO Laboratories (ENGL - see list in Annex I). The ENGL Consortium Agreement takes into consideration the two Regulations to address the needs for enforcement of the European food and feed legislation.

Most of the duties of the EURL-GMFF laid down in Article 32 of Regulation (EC) No 882/2004 are addressed by the regular activities of the EURL-GMFF and projects carried out within the MBG Unit:

- Official validated methods submitted in support to applications for authorisation under Regulation (EC) No 1829/2003 are published on the EURL-GMFF web site and related control samples are distributed to the members of the European Network of GMO Laboratories (ENGL);
- Scientific expertise in innovative detection approaches is constantly gathered, new tools are developed and diffused to ENGL members when relevant;
- Extensive training courses have been organised since 2000 for European control laboratories and third countries (e.g. Maghreb region) to provide analytical biotechnology skills and to promote the use of validated and harmonised methods for detecting, identifying and quantifying GMOs. An interactive DVD on GMO detection has been produced and a training manual has been edited in several languages (English, French, Spanish, Russian and Chinese). A compendium of validated methods for the detection of GMOs has been published;
- Based on the experience gained under Regulation (EC) No 1829/2003, the EURL-GMFF will continue to provide technical assistance to the Commission in case of dispute settlement or emergency measures;
- Observers from non-European countries participate in the ENGL meetings. Moreover capacity building and Pan-European networking is undertaken in collaboration with DG SANCO (project "Towards Global Harmonisation of GMO Analysis by Creating and Supporting Regional Networks of Excellence").

Specific projects to be carried out in 2012 and related to the responsibilities of the EURL-GMFF according to Regulation (EC) No 882/2004 would benefit from the financial support of the Commission.

2. WORK PROGRAMME

2.1. Overall objective

One of the main objectives of the EURL-GMFF in 2012 is to pursue in organising comparative testing rounds and to ensure appropriate follow up of NRLs based upon their results. This activity will be managed under the current EURL-GMFF quality system (ISO 9001 and ISO 17025). During its audit on 20 and 21 July 2011, the German accreditation body DakkS has recommended that the EURL-GMFF receives an ISO

17043 accreditation (for organisers of proficiency testing schemes). Due to the absence of the auditor specialised in the field of molecular biology, the accreditation certificate will be issued once this audit has taken place. The EURL-GMFF has urged the German accreditation body DakkS to schedule this visit at its earliest convenience.

The EURL-GMFF also intends to play a role in the harmonisation of ISO 17025 accreditation at European level in order to ensure that the accreditation process is homogeneous in the different countries in the context of GMO detection. Collaboration with the European Co-operation for Accreditation (EA) already started in 2010. The development of guidance documents for the detection and identification of GMOs is foreseen in 2012. These documents will be made available to NRLs for enforcement of the food and feed legislation in relation to GMOs.

2.2. Milestones and deliverables

2.2.1. Operation of the EURL-GMFF

(1.a) Quality assurance and management

The activities of the EURL-GMFF are managed in accordance with the ISO 9001 requirements as certified by “The Swiss Association for Quality and Management Systems (SQS)”, and for its technical activities under ISO 17025 accreditation granted by the Italian National Accreditation Body with a flexible scope for DNA Extraction and PCR Methods for the detection and identification of GMOs in food and feed materials.

In addition, as organiser of a comparative testing scheme, the EURL-GMFF has worked towards the accreditation according to the ISO 17043 standard. The EURL-GMFF has already implemented all the necessary procedures to achieve the accreditation according to this international standard (Table 1). On 20 and 21 July 2011 the EURL-GMFF has been audited by a team of two auditors one of which is specialised in ISO 17043 quality management systems and the other one in statistics. The ISO 17043 audit related to the molecular biology activities, still needs to take place.

Table 1: Quality assurance objectives and deliverables

<i>O.1.1</i>	To achieve and maintain official recognition of the quality system (ISO 17043 and ISO 9001:2000, ISO 17025:2005)
<i>D.1.1</i>	Annual audit – Date to be defined with the accreditation body

(1.b) Communication and Information technologies

The MBG Unit developed a web-based platform (ENGLnet) dedicated to ENGL members, through a secured intranet, for exchange of information and collaborative workspaces. NRLs have all been granted access to the ENGLnet and a specific workspace for activities related to Regulation (EC) No 882/2004 is constantly updated (Table 2).

The exchange of information between the EURL-GMFF and NRLs occurs during meetings/workshops, through the web-based platform and *ad-hoc* requests from NRLs.

Table 2: IT objective and deliverable

<i>O.2.1</i>	To update the ENGLnet specific workspace for NRLs and ensure regular exchange of information between the EURL-GMFF and NRLs.
<i>D.2.1</i>	EURL-GMFF activity report – March 2013

2.2.2. Organisation of comparative testing rounds

In 2012, the EURL-GMFF will pursue implementing Article 32.1.b of Regulation (EC) No 882/2004 by organising two comparative testing rounds, the first one being launched in spring 2012. The Advisory Board will continue to provide advice on the design of comparative testing rounds and will participate in the evaluation of the results and the subsequent follow up.

The participation in the comparative testing (CT) rounds is free of charge and mandatory for all NRLs appointed under Regulation (EC) No. 882/2004 and Regulation (EC) No 1981/2006. The ENGL members and laboratories from third countries will again be invited to participate in the CT rounds organised by the EURL-GMFF. In the frame of the capacity building and pan-European networking programme, entitled “Towards Global Harmonisation of GMO Analysis by Creating and Supporting Regional Networks of Excellence”, invited laboratories from third countries can volunteer to participate.

Each round will be composed of two samples containing a genetically modified (GM) event(s) at two different concentrations. One concentration will be around or even below the labelling threshold and the other concentration will be well above the labelling threshold. Each NRL will have to detect and quantify the GM event(s). The deadline for the submission of results will be six weeks.

In 2012, the first round will contain genomic DNA of rapeseed GT73 (Unique identifier MON-ØØØ73-7) and maize 59122 (Unique identifier DAS-59122-7) and the second round will be a compound feed stuff containing a mixture of two GM events, namely RoundUp Ready soybean (Unique identifier MON-Ø4Ø32-6) and maize MON 88017 (Unique identifier MON-88Ø17-3). In 2011, the EURL-GMFF started producing the test items for the comparative testing rounds in-house. In addition, a series of tests will be performed on each test item to determine the homogeneity and the stability of the test items. The EURL-GMFF will continue the collaboration with the Food Safety and Quality Unit (FSQ) of the Institute for Reference Materials and Measurements. The FSQ Unit will manage the on-line registration of participants and the submission of results.

The EURL-GMFF will follow up the comparative tests by providing NRLs with technical support and appropriate training in case results would fall outside the acceptance criteria (Table 3). This follow up will be managed in two phases:

- Phase 1

Whenever possible, the underperforming NRL will repeat the comparative test to conclude the assessment of results by the EURL-GMFF. At this stage, the Commission (DG SANCO) will be informed but confidentiality will be ensured (NRL identity encoded). The results of the CT round and the laboratory codes of NRLs will be included in the report on the comparative testing round sent to the Commission.

- Phase 2

If the results of the subsequent CT round still reveal underperformance of an NRL, the EURL-GMFF will contact the NRL, provide assistance on the quality system and procedures, and organise training if necessary. The Commission will be officially informed by the EURL-GMFF. The report on the comparative testing round will include the main findings and corrective action(s) to improve the analytical results. The Commission may decide to inform the Competent Authority to require that appropriate action(s) are taken with regard to the NRL.

Table 3: Comparative testing schemes objectives and deliverables

<i>O.3.1</i>	Meetings of the Advisory Board and minutes of the meetings
<i>D.3.1</i>	Technical and Financial reports (see Table 5)
<i>O.3.2</i>	Production of test materials and organisation of CT rounds
<i>D.3.2</i>	Final Reports on CT rounds – February 2013 and September 2013

2.2.3. Trainings and missions

In the context of the implementation of Article 32.1.b of Regulation (EC) No 882/2004 (organisation of CT rounds and follow up), several trips of 1-3 members of the MBG Unit are expected in 2012 to different European countries, to provide the technical support and training needed by NRLs.

2.2.4. Workshops and meetings of experts

NRLs will be invited to participate to one plenary meeting that will be organised by the Joint Research Centre (Ispra, Italy). In addition, two meetings of experts from the EURL-GMFF Advisory Board for Comparative Testing Schemes are foreseen in 2012 (Table 4).

Table 4: Workshop objectives and deliverables

<i>O.5.1</i>	Plenary meeting and meetings of the Advisory Board for CT
<i>D.5.1</i>	Workshop financial and technical reports – 2 months after each workshop

2.2.5. Human resources

The human resources that will be needed to implement the 2012 work plan of the EURL-GMFF in relation to Regulation (EC) No 882/2004 are shown in Table 5.

Table 5: EURL-GMFF staff table

Category	Status	Time allocated
Head of Unit – AD	F	5 %
Scientific officer – AD	F	80 %
Scientific officer – AD	F	10 %
Quality manager – AST	F	10 %
IT developer – AST	F	5 %
Grant Holder	GH	100 %
Scientific and technical support officer – FGIII	CA	100 %
Secretary – FGII	CA	100 %

ANNEX I

List of NRLs nominated under Regulation (EC) No 882/2004

MS	Organisation
AT	Austrian Agency for Health and Food Safety (AGES), Competence Centre for Biochemistry.
AT	Environment Agency Austria
BE	Scientific Institute of Public Health (IPH)
BE	Institute for Agricultural and Fisheries Research (ILVO)
BE	Walloon Agricultural Research Centre (CRA-W) - Department Valorization of Agricultural Products (D4) - Unit 16 -
BG	National Center of Public Health Protection - Bulgarian National Laboratory for Genetically Modified Food
CY	State General Laboratory
CZ	Crop Research Institute - Reference Laboratory for GMO Detection and DNA fingerprinting
DE	Federal Office of Consumer Protection and Food Safety- Berlin
DK	Danish Plant Directorate, Laboratory for Diagnostics in Plants, Seed, and Feed
DK	National Food Institute
ES	Laboratory Agroalimentary of the Spanish Ministry of the Environment and Rural and Marine Affairs
ES	National Centre for Food, Spanish Food Safety Agency and Nutrition
FI	Finnish Customs Laboratory
FR	Plant Health Laboratory
FR	Service Commun des Laboratoires du MINEFI - Laboratoire de Strasbourg
FR	BioGEVES - Groupement d'Intérêt Public – Groupe d'Etude et de contrôle des Variétés et des Semences
GR	Ministry of Finance, General Secretariat for Tax and Customs Issues, General Chemical State Laboratory (GCSL),
GR	Ministry of Finance, General Secretariat for Tax and Customs Issues, General Chemical State Laboratory (GCSL),
GR	Genetic Identification Laboratory (G.I.L) of the National Agricultural Research Foundation (NAGREF)
HU	Central Agricultural Office, Food and Feed Safety Directorate - Laboratory for GMO Food
HU	Central Agricultural Office, Food and Feed Safety Directorate, Feed Investigation National Reference Laboratory
IT	Veterinary Public Health Institute for Lazio and Toscana Regions; National Reference Centre for GMO Analysis
LT	National Food and Veterinary Risk Assessment Institute, Laboratory Department, Molecular Biology and GMO Section
LU	National Health Laboratory, Food Control Department
LV	Institute of Food Safety, Animal Health and Environment "BIOR"
NL	RIKILT Institute of Food Safety
PL	National Veterinary Research Institute in Pulawy, Department of Feed Hygiene
PL	State Sanitary and Epidemiological Station, Regional Laboratory of Genetically Modified Food
PL	National Research Institute of Animal Production, National Feed Laboratory in Lublin
PT	National Institute of Biological Resources, I.P./INIA - Food technology Unit
RO	Institute for Diagnosis and Animal Health, Molecular Biology and GMOs Unit
SE	National Food Administration
SI	National Institute of Biology
SK	State Veterinary and Food Institute Dolny Kubin
SK	Central Control and Testing Institute of Agriculture
UK	LGC Limited
UK / MT	LGC Limited - interim for MT
UK / IE	Food and Environment Research Agency (FERA) - interim for IE